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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/694,641
Filing Date: October 27, 2003
Appellant(s): KROETZ ET AL.

Deanna L. KROETZ et al.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 09, 2008 appealing from the Office action mailed September 17, 2008.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the board's decision in the pending appeal. The related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct

This appeal involves claims 46 and 48.

(4) Status of Amendments

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on November 26, 2008 has been acknowledged and entered in the Advisory Action mailed on December 12, 2008.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to Be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal in the brief is correct.

The ground(s) for rejection to be reviewed is/are:

Claims 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,962,455. This rejection is set forth in prior Office Action, mailed September 17, 2008.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct. In this application, no evidence has been submitted pursuant to §§ 1.130, 1.131 or 1.132 of this title or any evidence entered by the examiner and relied upon by appellant in the appeal.

***(8)* Evidence Relied Upon**

5,962,455	BLUM et al.	10-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Blum et al. (US 5962455).

Blum teaches use of compounds (e.g., RN 202472-67-1, RN 202472-68-2, RN 202472-69-3, RN 202472-70-6,etc…) or their salt, which reads on the instantly claimed compounds of the formula 1, for the treatment of the claimed cardiovascular disease such as hypertension or

essential hypertension as well as congestive heart failure, wherein said compound is administered in dosage amounts of from about 0.1mg to about 140mg per kilograms of body weight per day and in various dosage forms including oral dosage form (abstract; column 1, line 39; column 1, line 45 thru column 3, line 15; column 7, line 51; column 8, line 52 thru column 10, line 62).

(10) Response to Argument

Appellants' arguments/declarations filed 06/02/2008 and declarations filed 06/13/2006 and 02/23/2007 have been fully considered but they are not persuasive.

Appellants in his argument filed 06/02/2008 take the position that it is improper for the Office to ignore or disregard an express structural limitation set forth in both claims 46 and 48 "...wherein R^1 and R^3 are each independently selected from the group consisting of C_1-C_{20} substituted or unsubstituted alkyl, cycloalkyl, aryl, acyl, and heterocyclic". Appellants assert that the clause recited in claims 46 and 48 is an express structural limitation which limits the R^1 and R^3 substituents on both sides of the urea core to C_1-C_{20}, regardless of whether it is a substituted or unsubstituted alkyl, cycloalkyl, aryl, acyl, and heterocyclic.

This argument is not found persuasive. The reasonable interpretation of alternative expression recited in both Markush-type claims 46 and 48 refers to members as being selected from "C_1-C_{20} substituted or unsubstituted alkyl" alternative, "cycloalkyl" alternative, "aryl" alternative, "acyl" alternative or "heterocyclic" alternative. In other words, the appellants' interpretation of the clause recited in claims 46 and 48 as to "R^1 and R^3 substituents on both sides of the urea core to C_1-C_{20}" is in serious error. As discussed in the previous response (page 7, 1st paragraph of O.A. mailed 02/07/2008), there is no indication in the instant claims 46 and 48 that

R^1 and R^3 must be essentially in C_1-C_{20}. Rather, the instant claims allow for inclusion of "cycloalkyl, aryl, acyl and heterocyclic" as R^1 and/or R^3 alternative species. Thus, the examiner maintains that Blum's compounds read on the instant compounds represented by the structure formula depicted in claims 46 and 48 (when R1 and R3 are "aryl").

Appellants in his argument filed 06/02/2008 take the position that the substituted benzylamine derivative compounds disclosed by Blum are unlikely to inhibit sEH activity rather than necessarily inhibit sHE because of the structural unrelatedness of human NPY1R and human sEH proteins and bulkiness of at least one of the substituents (i.e., the substituent that has more than 20 carbons). Appellants allege that Exhibits submitted on June 02, 2008 and Dr. Bruce Hammock's Declaration submitted on June 13, 2006 and February 23, 2007 confirm that the substituted benzylamine derivative compounds of Blum are unlikely to inhibit the enzymatic activity of sEH.

This argument is not found persuasive. With respect to Dr. Hammock's Declaration, the examiner likes to point out that there is no conclusive statement or data showing that the compounds of Blum do not show any inhibitory activity of sHE. Rather, Dr. Hammock stated that the referenced compounds (e.g., compound RN 202472-69-3 and RN 202472-70-6) could be "mediocre activity" (see page 7 of Declaration filed 06/13/06). In other words, it is clear from Dr. Hammock's statement that the compounds of Blum possess some degree (little to moderate) of sEH inhibitor activity. Since the instant claims 46 and 48 do not specifically recite how much of sEH enzymatic activity is required to practice the claimed invention, the prior art directing the administration of the same compound in overlapping dosage amounts (see "0.001 μM/kg to

about 100mg/kg body weight" in para. [0060] of the instant specification) inherently possessing therapeutic effects for the same ultimate purpose (e.g., the treatment of hypertension) as disclosed by the applicant clearly anticipates the claimed invention even absent explicit recitation of underlying mechanism.

Even assuming arguendo that the certain degree of sHE enzymatic activity (for example much less with an IC50 of less than 500 μM or an IC50 of less than 17.8 μM as the applicant alleged) is critical for the claimed invention, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it not inventive to discover the optimum or workable particle distribution percentage or concentration by routine experimentation.

(11) Related Proceeding(s) Appendix

The appellant's statement of related proceedings appendix in the brief is correct. There are no decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c) (1) (ii) of this section.

For the above reasons, it is believed that the rejection(s) should be sustained.

Respectfully submitted,

Brian Kwon:bk
February 24, 2009

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614

Conferees
Ardin Marschel, Dave Nguyen

/Dave Nguyen/